received: adalimumab 40 mg every other week (eow) + MTX; adalimumab 40 mg eow; or MTX monotherapy. The Short Form 36 (SF-36) was used to assess 8 domains of HRQOL at baseline, and after 12, 26, 42, 52, 76, and 104 weeks of therapy (higher scores indicate improvement). Scores for 4 physical and 4 mental health concepts were aggregated into Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. A minimum clinically important difference (MCID) is 2.5–5.0 for PCS and MCS. Criteria-based interpretation of the PCS evaluated relationships between clinically and socially meaningful variables. **RESULTS:** Baseline scores for the 799 patients were comparable between all 3 groups, and post-baseline results were comparable for the 2 monotherapy groups. Mean baseline PCS for the adalimumab + MTX (n = 256) and MTX monotherapy (n = 247) groups were 31.7 and 32.2. Mean PCS for the combination therapy group at Week 12 had improved to 42.2 vs. 38.2 for the MTX group. The 4.5 difference in mean change from baseline was clinically meaningful and sustained through 2 years (5.1) ($p < 0.0001$). Based on criteria-based interpretation of the SF-36, differences in PCS scores between the 2 groups indicate patients on MTX alone had an increased likelihood of using more health resources and not being able to work. **CONCLUSIONS:** Adalimumab + MTX were superior to MTX alone in providing significant and clinically meaningful improvements in HRQOL in early RA. Significantly lower PCS at 2 years in the MTX group may mean patients on MTX alone have greater health care utilization and substantially greater job loss than patients on combination therapy.

PAR20

EFFECTS OF LONG-TERM ADALIMUMAB THERAPY ON HEALTH UTILITY AND FATIGUE IN PATIENTS WITH LONG-STANDING, SEVERE RHEUMATOID ARTHRITIS (RA)—RESULTS FROM A 3-YEAR FOLLOW-UP STUDY

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OBJECTIVES: To investigate the ability of adalimumab therapy to provide simultaneous, sustained long-term improvement in two important patient-reported outcomes (health utility and fatigue) in patients with severe RA who had failed at least one DMARD. **METHODS:** The Health Utilities Index Mark 3 (HUI3) and Fatigue (FACIT-F, validated in RA) were simultaneously measured in a health economics companion trial to an adalimumab pivotal study (DE011). For the first 26 weeks patients were followed under double-blind, randomized conditions before rolling over into a long-term, open-label extension (OLE) (n = 99). A subset of patients receiving adalimumab 40 mg every other week was evaluated for up to 170 weeks. The HUI3 scale is 0–1, with "1" denoting perfect health and "0" denoting death. FACIT-F scores range from 0–52, with higher scores representing less fatigue. Changes in HUI3 of ≥0.03 and FACIT-F of ≥4 are considered clinically meaningful. **RESULTS:** Baseline patient characteristics were: female, 80%; age, 53 years; duration of disease, 10 years; TJC (0–68), 34; SJC (0–66), 21; HAQ score, 1.9; C-reactive protein (mg/L), 54; number of previous DMARDs: 4 (all mean values except % female). RA patients' baseline utility and fatigue scores were comparable (vs. placebo) and approximately one-third of the population norm. At week 26, mean changes from baseline in adalimumab-treated patients were 0.18 for HUI3, and 8.54 for FACIT-F (both $p <$ 0.001 vs. baseline). These improvements were sustained throughout week 170. **CONCLUSIONS:** Adalimumab provided clinically important, simultaneous improvements in health utility and fatigue in patients with severe, active RA who had failed at least one DMARD. These improvements were sustained over the 3-year observation period.

ASTHMA

PAS1

COMPARISON OF TREATMENT WITH BUDESONIDE/FORMOTEROL (BUD/FM) PLUS BUD/FM PRN AS SINGLE INHALER TREATMENT VERSUS REGULAR BUD AND FM PLUS FM PRN AS MONOPRODUCTS IN PATIENTS WITH ASTHMA IN GREECE

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OBJECTIVE: To compare the efficacy of regular treatment with BUD/FM plus BUD/FM prn versus regular treatment with budesonide (BUD) and formoterol (FM) plus FM prn in the treatment of asthmatic patients in Greece. **METHODS:** Moderate asthmatic (mean FEV1 76% pred.) patients were recruited from 14 centers in Greece to participate in an open-label, randomized prospective clinical trial. The duration of the study was seven months with four scheduled visits: baseline, first month, third month and seventh month. Patients were randomized in 2 groups: Group A: BUD/FM 160/4.5 ìg bid plus BUD/FM prn and Group B: BUD 200 ìg and FM 9 ìg bid plus FM prn. Outcome measures included lung function, number of exacerbations and relief inhalations, symptom control using the Asthma Control Questionnaire (ACQ) and quality of life using the Asthma Quality of Life Questionnaire (AQLQ). In addition, the use of health services and side effects were recorded. **RESULTS:** A total of 133 patients were recruited, 68 in Group A, and 65 in Group B. Both groups showed a significant improvement in ACQ at the end of the study ($p < 0.0001$). Relief inhalations were significantly less in Group A ($p < 0.0001$) during the last study period, between 3rd and 7th month. No statistically significant differences were found in the other outcome measures. **CONCLUSIONS:** BUD/FM therapy plus BUD/FM as needed demonstrated similar effectiveness in asthma control and quality of life compared to treatment with BUD and FM plus FM as needed. Since fewer relief inhalations were recorded in Group A, BUD/FM plus BUD/FM prn treatment seems preferable for patients with asthma.

PAS2

FLUTICASONE PROPIONATE/SALMETEROL COMBINATION IMPROVES HEALTH OUTCOMES AND QUALITY OF LIFE IN CHILDREN WITH POORLY CONTROLLED ASTHMA IN IRELAND

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OBJECTIVE: To investigate whether salmeterol/fluticasone propionate 50/100 mcg (SFC) improves quality of life, physical functioning and asthma symptoms in children with uncontrolled asthma in primary care. **METHODS:** A prospective open label study of children seven to twelve years old attending their GP with uncontrolled asthma. SFC bd was taken for 16 weeks (w) from enrolment. Peak expiratory flow rate (PEFR) was measured at baseline, w4 and w16, when the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) was completed. Patient diaries

recorded symptom scores, use of rescue medication, and time off school and parental time off work due to asthma. **RESULTS:** A total of 35 patients participated. Mean age: 9.8 yrs, mean time since diagnosis: 6.2 yrs. At w16 compared with w0: Mean PEFR increased by 59.2 l/min*; all PAQLQ domain and overall scores improved >=2 points*; mean day and night time symptoms scores improved by 1.5 points* and 1.6* points respectively; patients reported a mean of 3.9 more days per week without asthma symptoms* and 4.6 fewer days per week using short acting β2 agonist medication*; children missed 1.6 fewer school days per month, and carers missed a mean of 1.2 fewer days per month from work*. No treatment related adverse events were reported. **CONCLUSION:** SFC significantly improved asthma symptoms, quality of life and daily activities of uncontrolled pediatric asthma patients and their families. *P < 0.05

PAS3

ASTHMA CONTROL IN SPAIN. DOES TREATMENT PROFILE AND SEASON MATTER?

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OBJECTIVE: The aim of this study was to assess the degree of asthma control in Spain in accordance with the GINA criteria. **METHODS:** An epidemiological cross-sectional multicenter study was performed. A representative sample of consecutive patients with asthma over 18 years attending primary care and specialist offices were enrolled. Patients were seen in winter and spring and were asked on their asthma control in the four weeks prior to the visit according to the GINA criteria. Control was defined based on the patient's day and night symptoms. **RESULTS:** A total of 614 patients participated in the study. Patients presented every day or most days in the four weeks prior to the winter and spring visit daytime symptoms (40.3% vs. 22.5%) ($p < 0.01$), night-time symptoms (27.8% vs. 13.9%) ($p < 0.01$)), severe exacerbation episodes (11.9% vs. 8.8%) and intolerance to exercise (32.9% vs. 35.5%). The proportion of patients with emergency visits in the four weeks prior to the visit was 9.1% vs. 4.2% ($p < 0.01$) respectively. The most frequently used treatment was the combination of inhaled corticosteroids and long-acting b2 adrenergic agonists (49.8% vs. 49%). There were a slightly higher number of inadequately controlled patients in winter than spring, 74.2% vs. 71.1% ($p < 0.01$) respectively. **CONCLUSION:** Asthma is poorly controlled in Spain, with the need for improvements in the management of the disease.

PAS4

THE COST OF ASTHMA EXACERBATIONS OF DIFFERENT SEVERITY LEVELS

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OBJECTIVES: A literature search revealed only a few published retrospective database analyses in which the yearly cost of asthma was compared for patients with and without asthma attacks. This however does not allow estimating the health care utilization associated with a single exacerbation. In contrast, this study aims to analyze resource use collected during a randomized, double-blind trial and to estimate the costs of a mild and a severe asthma exacerbation. **METHODS:** The INNOVATE trial randomized severe persistent allergic asthma patients who were inadequately controlled despite inhaled corticosteroid (ICS) and long-acting beta2-agonist (LABA) to continued standard therapy (N = 210) or to add-on therapy with omalizumab (N = 209). Resource use was recorded on the CRF and with daily patient diaries. Data from both treatment arms were pooled to calculate average resource use for clinically significant (worsening of asthma symptoms requiring systemic steroids) mild (PEF or FEV1 >= 60% of personal best) or severe (PEF or FEV1 < 60% of personal best) exacerbations from a UK NHS perspective. Patients were observed for a total of 36 weeks (including 8 weeks run-in). Standard unit costs (PSSRU, NHS Reference Costs, 2004) were applied to calculate the exacerbation-related cost. **RESULTS:** A total of 419 patients experienced 195 mild and 204 severe exacerbations during the observation period, lasting on average 12.8 days each. Resource use was measured in terms of GP surgery visits, ER visits, outpatient visits, hospitalizations and rehabilitation visits. The average cost of a clinically significant mild exacerbation is estimated to be £99, and of a severe exacerbation is £197. **CONCLUSIONS:** Exacerbations are costly and frequently occurring events in a severe persistent allergic asthma population. Decreasing the frequency and severity of exacerbations improves patients' health outcomes and reduces resource use, which could be quantified with this approach.

PAS5

IMPACT OF MONTELUKAST THERAPY ON ASTHMA-RELATED HEALTH CARE RESOURCES USE IN MILD TO MODERATE ASTHMATIC PATIENTS WITH SEASONAL ALLERGIC RHINITIS IN SPAIN

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Montelukast is recognised to be an effective and safe therapy for the treatment of mild to moderate asthmatic patients with concomitant seasonal allergic rhinitis. **OBJECTIVES:** to evaluate asthma-related direct costs in patients with mild to moderate persistent asthma and seasonal allergic rhinitis (AR) in Spain, whose asthma was inadequately controlled and required the addition of montelukast as part of their routine care. **METHODS:** a multicenter, 12 months pre-post observational study was conducted, selecting mild to moderate asthmatic consecutive patients with previous inhaled corticosteroid (ICS) w/wo LABAs therapy, who initiated concomitant montekulast between January 1999 and December 2002. Asthma-related health care resources data was collected retrospectively, including medication, medical visits, ER visits and hospitalizations. For the costing calculations, natural units were multiplied by unit costs, and confidence intervals (CI) calculated using bootstrapping analysis. **RESULTS:** 212 patients (mean age 36.0(SD 9.7), 56.6% female, 50.9% mild asthmatics) were recruited in 55 sites (54.5% Primary Care, 34.5% Allergologists and 11% Pneumologists) across the country. After initiation of montelukast therapy, all other asthma-related health care resource categories did show a significant reduction ($p < 0.01$) (mean reduction in 2004€; 95% CIs): medication (146.1; 78.8–225.2); outpatient visits (57.5; 44.5–76.8), ER visits (61.1; 48.4–84.4) and hospitalizations (243; 86.2–875.4), total 508.3 95% CI 348.3–969.9. Additionally considering the montelukast treatment cost during 365 days, the reduction achieved in all other asthma-related health care resources would compensate for 92.7% of the montelukast cost. **CONCLUSIONS:** montelukast therapy was associated with a significant reduction in all other asthma-related health care resources use in patients with mild to moderate asthma and concomitant seasonal allergic rhinitis.